Exhibit C

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VIA EMAIL

Special Master David R. Cohen
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Re: Retail Pharmacy Defendants' Submission re Trinity Cocktails

Dear Special Master Cohen:

We write on behalf of the Track 1B Retail Pharmacy Defendants[1] (the "Pharmacy Defendants") concerning Plaintiffs' request that, in addition to producing dispensing data for the agreed-upon opioids, the Pharmacy Defendants produce dispensing data for additional drugs in connection with Plaintiffs' assertion that certain so-called "cocktail" or "Trinity" drugs, may, in certain instances, constitute a "red flag" to a pharmacist filling an opioid prescription. As explained further below, the Pharmacy Defendants submit that any additional dispensing data be limited to data concerning the "Trinity" or "Holy Trinity" combinations, described by DEA in the context of enforcement efforts and by the Ohio Board of Pharmacy, as consisting of (1) alprazolam; (2) carisprodol; and (3) either oxycodone or hydrocodone. The Pharmacy Defendants further submit that any dispensing data concerning this combination of drugs must be limited to that which is (1) filled on the same day at the same store, (2) for the same patient, (3) prescribed by the same prescriber, and (4) dispensed in 2013 and later.[2]

[1] The Track 1B Retail Pharmacy Defendants include: CVS, Discount Drug Mart, HBC/Giant Eagle, Rite Aid, Walgreens, and Walmart.

[2] By making this submission as directed by Special Master Cohen on January 23, 2020, the Pharmacy Defendants do not concede that any prescriptions meeting this definition would constitute a "red flag" or not be medically necessary.

There Is No Blanket Regulatory Prohibition for Combination Prescriptions

When asked for its position regarding "Trinity" prescriptions, DEA advised that "[f]ederal regulations do not define the term legitimate medical purpose nor do they set forth the standards of medical practice. It is up to each DEA-registered practitioner to treat a patient according to his or her professional medical judgment . . . . DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine. . . . DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or the duration of treatment intended with the prescribed controlled substance." Ex. A (Nov. 4, 2019 DOJ/DEA letter to NACDS), at p. 1-2.

Indeed, the Controlled Substances Act ("CSA") and its regulations do not contain any explicit reference to "red flags" that might suggest a prescription was not written for legitimate medical purposes, much less any definition of what constitutes a "cocktail" or "Trinity" combination. Nor is any definition specified in any Ohio regulation or statute. Rather, DEA regulations for implementing the CSA assign responsibility for the proper prescribing of controlled substances to the prescribing practitioner and assign a "corresponding responsibility" to the pharmacist filling a controlled substance prescription. 21 C.F.R. § 1306.04. In the context of CSA enforcement, the DEA has used the concept of "red flags" to describe circumstances about which a reasonable pharmacist—in keeping with his or her "corresponding responsibility"—may want to be aware. One such "red flag" involves "Trinity" prescriptions.

DEA and Ohio Board of Pharmacy Guidance Regarding "Trinity" Prescriptions

Starting in approximately 2012, DEA identified a specific combination of prescriptions as the "Trinity" or "Holy Trinity" in guidance presentations. *See* Ex. B (Aug. 3 & 4, 2013 DEA presentation on DEA Perspective: Pharmaceutical Use & Abuse, during the Baton Rouge Pharmacy Diversion Awareness Conference), at p. 18, 20; Ex. C (Aug. 24, 2015 DEA presentation on Current Trends in DEA Compliance, to NACDS), at p. 3, 9; Ex. D (March 19 & 20, 2016 DEA presentation on DEA Trends and Update, to the Delaware Pharmacy Diversion Awareness Conference), at p. 33-35; Ex. E (2017 DEA presentation on DEA Trends and Update, to San Juan Delaware Pharmacy Diversion Awareness Conference), at p. 12, 17, 18. One of these presentations was made directly to chain pharmacies in 2015. *See Ex*. C (DEA presentation directed to NACDS).[3]

[3] The date range for these productions should be limited to 2013 and later, i.e., a few months after the 2012 DEA guidance regarding "Trinity" prescriptions and more than two years before the cited 2015 presentation to chain pharmacies and 2015 Ohio Board of Pharmacy guidance.

These presentations consistently use the terms "Trinity" and "Holy Trinity" synonymously with "cocktail" and define the combination as comprising three products: (1) either hydrocodone or oxycodone, (2) alprazolam (Xanax®) (a benzodiazepine), and (3) carisoprodol (Soma®) (a muscle relaxant). Removing any doubt, in its recent decision in *Trinity Pharmacy II*, DEA makes clear that "red flag" cocktail prescriptions consist of an opioid, a benzodiazepine, and a muscle relaxant at once. 83 Fed. Reg. 7304, 7318 (Feb. 20, 2018) ("'cocktail prescriptions'… occur[] when a customer presents multiple prescriptions that would provide the same patient an opioid, a benzodiazepine, and a muscle relaxer"); *see also id*. at 7312, 7316 n. 29, 7319, 7326, 7332.

Similarly, the Ohio Board of Pharmacy website includes a June 2015 video on the red flags of prescription drug diversion, which defines a "cocktail" as a three-drug combination of an opioid, a benzodiazepine, and a muscle relaxant. *See* Ohio Board of Pharmacy video at 5:55-6:20.[4] The video further defines "Trinity" as the combination of hydrocodone, alprazolam, and carisoprodol, and the "Holy Trinity" as the combination of oxycodone, alprazolam, and carisoprodol. *Id.* Notably, neither the DEA nor Ohio Board of Pharmacy has asserted that *any* opioid combinations are per se impermissible or even constitute unresolvable red flags—let alone Trinity combinations.

Pharmacy Defendants' Position Regarding "Trinity" Combination Dispensing Data

The Pharmacy Defendants submit that any obligation to produce dispensing data pertaining to purported opioid combination prescriptions must be limited to data concerning the "Trinity" or "Holy Trinity" combinations, as defined by DEA and the Ohio Board of Pharmacy. The production of data must be further limited to data concerning prescriptions for only those combinations that were written on the same day, by the same prescriber, and for the same patient. These additional limitations are consistent with the guidance promulgated by the Ohio Board of Pharmacy. *See* Ohio Board of Pharmacy video at 6:20-7:02 (depicting a single prescription for all drugs being handed by one patient to the pharmacist). Furthermore, unless the combination is presented to the pharmacist at the same time, it might not be apparent that there might be a red flag to resolve. For example, a reasonable pharmacist may not believe there is cause to investigate further when presented with a single prescription for carisoprodol only. Prescriptions for individual "Trinity" components may be presented, given the role those drugs play (both individually and in combination with each other) in the treatment of, for example,

[4] The video can be found at https://www.pharmacy.ohio.gov/ or on the Ohio Board of Pharmacy YouTube account: https://www.youtube.com/channel/UCidYeMX_wTBJsAVgafF076g.

cancer patients, conditions involving muscle spasms, debilitating conditions, anxiety, and palliative care.

The Pharmacy Defendants' proposed additional limitations are also critical to help ameliorate the significant burden involved with producing dispensing data for both opioids and non-opioids and protecting patient privacy by limiting the production of dispensing data to the minimum necessary for this case.

Pharmacy Defendants' Response to Plaintiffs' Proposal

Plaintiffs' proposed drug list (enclosed as Ex. G), contains 43 drugs, including at least one opioid (buprenorphine) that was not agreed to as a relevant opioid in Track 1 and was never a Schedule II drug,[5] and several drugs that are not even controlled substances. That list is overly broad, impractical, and would implicate many common drug combinations that are frequently prescribed for legitimate treatment purposes—such as the combination of a sleep aid and opioid, which would be typical treatment for a patient coming out of surgery.

Furthermore, Plaintiffs' request (announced for the first time on the January 23 teleconference) for data on any combination of 2 of the 43 drugs over a 30-day period is also overbroad and would be extremely burdensome to implement in the discovery context. The Pharmacy Defendants cannot commit to being able to produce that volume of data by the March 2 deadline provided by the Special Master during the parties' January 22 meeting. It is also divorced from reality, as it suggests counterfactually that pharmacists are somehow required to recognize any of the thousands of purported red flag combinations that might result from Plaintiffs' list. By definition, "Trinity" refers to three and not two.

Plaintiffs' proposal not only is inconsistent with the aforementioned DEA and Ohio Board of Pharmacy authorities, but it also lacks support in the sources that Plaintiffs cite. The August 31, 2016 FDA Drug Safety Communications (attached as Ex. H) cited by Plaintiffs during the January 23 teleconference has no reference to DEA "red flags" or pharmacists' corresponding responsibility. Rather, it is a safety announcement directed to prescribers and patients.

Further, the Sixth Circuit case that Plaintiffs quoted during that teleconference, *U.S. v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994), has nothing to do with Schedule II opioids and, thus, is entirely inapposite to this dispute. *See U.S. v. Veal*, 23 F.3d 985 (affirming illegal distribution of controlled substances conviction of pharmacist who made "inordinately large purchases" of two

[5] Buphrenorphine is used in the treatment of addiction and raises additional serious privacy concerns.

specific Schedule III drugs, Doriden and Tylenol 4). And notably, Plaintiffs have identified no support for their request for data showing prescriptions in the same 30-day period, although the Pharmacy Defendants specifically asked for that support during the January 23 teleconference.

Plaintiffs' Reliance on Pharmacy Defendants' Internal Guidelines

Plaintiffs' reference to certain Pharmacy Defendants' guidelines for assisting pharmacists in exercising their corresponding responsibility is also misplaced. Moreover, some of the internal company guidelines that Plaintiffs cite are *not* used to identify prescriptions that should not be filled. *See* Ex. I (Plaintiffs' First Combined Discovery Requests to Dispensers, at Request No. 2, n.1, which cites statistical metrics used in monitoring wholesale orders). In other words, the measures are neither used nor designed for the purpose Plaintiffs suggest. Rather, they are considered for broader monitoring purposes—for instance, as a statistic to evaluate wholesale ordering or to assess whether a doctor should be subject to a company's prescriber monitoring program.[6]

Regardless, the law is clear that an internal corporate policy does not create a legal duty. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig*., 2016 WL 807377, at *8 n.22 (E.D. Pa. Mar. 2, 2016) (excluding portion of expert's opinion attempting to use Johnson & Johnson's Credo regarding a commitment to patients to show the appropriate "standard of care," and holding that "[a]llowing the company to be judged on this standard of care could discourage companies from creating internal policies that go beyond what the law asks")

Patient Privacy and Federal Rule of Civil Procedure Proportionality Considerations

Federal Rule of Civil Procedure 26 instructs the Special Master not only to limit discovery to what is relevant, but also to consider whether the discovery sought is proportional to the needs of the case. *In re Ohio Execution Protocol Litigation*, 845 F.3d 231, 236 (2016) ("[A] plaintiff [cannot] be permitted to go fishing and a trial court retains discretion to determine that a discovery request is too broad and oppressive."). In applying that analysis here, the Special Master must also take into consideration the fact that dispensing data is highly sensitive patient medical data that should be produced only to the extent necessary. The Pharmacy Defendants have already been ordered to produce an extraordinary amount of sensitive dispensing data. Plaintiffs' proposal would impose yet another significant burden on the Pharmacy Defendants to

[6] Even if the Special Master were to adopt such an inapposite measure, it is expressly limited to cocktail prescriptions filled "at the same store on the same day." *See* Ex. J (CVS-MDLT1-412, which was cited by Plaintiffs in their First Combined Discovery Requests at n.1). Plaintiffs should not be permitted to impose the aspects that suit them and simultaneously discard those that do not.

craft complex queries to identify data for thousands of combinations involving opioids and non-opioids. Plaintiffs' proposal would also increase the amount of dispensing data (and, thus, sensitive patient data) that would be produced, not to mention the time it would take to produce the data. Plaintiffs' proposal should be rejected.

Very truly yours,

/s/ Tara A. Fumerton

Tara A. Fumerton

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